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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,656	02/05/2004	Juan Saus	03-075-US	6152

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EXAMINER	
HALVORSON, MARK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,656	SAUS ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,24,34-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,24 and 34-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/13/2004; 12/13/2*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants election with traverse of Group VIII is acknowledged. Applicants cancellation of claims 1-21, 23, and 25-33 and the addition of claims 34-41 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the restriction has been maintained. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 22, 24 and 34-41 are under examination.

Sequence Rules

2. The specification is objected because it fails the sequence rules. This application contains sequence disclosure (see claim 22) that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. 37CFR 1.821(a) presents a definition for "nucleotide and/or amino acid sequences." Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. "Specifically

defined" means those amino acids other than "Xaa" and those nucleotide bases other than "n" defined in accordance with the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (1998), including Tables 1 through 6 in Appendix 2 (see MPEP § 2422). In addition, 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application.

The sequence, X1-SHCIX2-X3, listed in claim 22 and at page 33, line 17 of the specification is not provided with a SEQ ID NO:. Applicant must provide the sequence with a SEQ ID NO: and supply a substitute version of the Sequence Listing and a CRF copy of the Sequence Listing with the reply to this Office Action.

Claim Objections

3. Claim 22 is objected to because of the following informalities: X2 in line 4 of claim 22 appears to be X3 because there are two entries for X2 that are separated by the conjunction "and". For purposes of this Office Action, X2 in line 4 is interpreted as X3. However, this treatment does not relieve applicant the burden of responding to this objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 22, 24, 34-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 is drawn to an isolated polypeptide consisting of X1-SHIX2-X3 wherein X1 is 0-10 amino acids of the sequence ATTAGILATL; wherein X3 is 0-10 amino acids of the sequence LMVKREDSWQ. It is not clear whether Applicant intends the 0-10 amino acids of X1 and X3 for the polypeptide of claim 22 be contiguous or non-contiguous. In addition it is not clear whether Applicant intends that the 0-10 acids of X1 and X3 be any contiguous sequence or contiguous from the terminus closest to the core sequence only, i.e. the C terminus of X1 or the N terminus of X3. That is, does Applicant intend that the amino acid sequence of X1 be restricted to the sequences ATTAGILATL, TTAGILATL, TAGILATL, AGILATL, GILATL, etc.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 24, 38-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 1 12, first paragraph, have been described by the court in In re Wands, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

Claims 24, 38-41 are drawn to pharmaceutical compositions comprising isolated polypeptides and a pharmaceutically acceptable carrier. A pharmaceutical composition implies an in vivo use.

The specification discloses that the peptide can be used in a method for treating an autoimmune disorder, a tumor, a protein deposit-mediated disorder and/or prevent cell apoptosis (page 32, lines 30-31). The peptide was identified using a yeast two-hybrid system and cDNA deletion mutants of the Goodpasture antigen-binding protein (GPBP) (page 61, lines 4-6). A synthetic peptide with the sequence LATLSHCIELMVKR (Q_2) inhibited GPBP autophosphorylation and cell conformer production (page 61, lines 6-13). A Q_{2d} peptide inhibited aggregation of GPBP with bovine PrP^c in vitro (page 64 lines 19-20). No experiments were disclosed to determine the effect of the peptide in vivo.

One cannot extrapolate the teaching of the specification to the scope of the claims because the specification teaches the ability to the peptide to inhibit aggregation of the GPBP in vitro while the claims recite the in vivo use of the peptide.

Applicants' claim an in vivo method for the treatment of an autoimmune disease, such as Goodpasture's disease, or cancer.

As drawn to the use of the peptide for the treatment autoimmune disease, such as Goodpasture's disease, and cancer, as contemplated by the specification and inferred by claims 24, 38-41, one cannot extrapolate the teaching of the specification to the scope of the claims because it is well known in the art that the art of autoimmune therapy and anticancer drug discovery for cancer therapy are highly unpredictable.

Few successful therapies for autoimmune disorders in humans have been found (see Abstract, Feldmann et al, Nature 435:612-619, 2005). Furthermore, treatment modalities for Goodpasture syndrome remain controversial and vary among

practitioners (see Abstract, Fox et al Nephrol Nursing J 28:305-310, 2001). Gura (Science, 1997, 278:1041-1042) teaches that researchers face the problem of sifting through numerous potential anticancer agents to find ones promising enough to make human clinical trials worthwhile and teach that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but that only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second para). Because of the known unpredictability of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed peptide could function as contemplated in the specification and inferred in claims 24, 38-41, that is could be used to treat autoimmune disease, cancer or, by extrapolation, any other disease, based only on the finding that the peptide inhibits aggregation and autophosphorylation of the GPBP in vitro.

In particular, the art also teaches general problems with the administration of peptide and protein drugs, namely short half-life in vivo, necessitating multiple administrations (Johnson and Tracey, 'Peptide and Protein Drug Delivery', In: Encyclopedia of Controlled Drug Delivery, Vol. 2, 1999, pages 816-833). The art teaches that major stability, release and manufacturing challenges" (page 816, second column, lines 1-5) must be met in order to overcome the technical difficulties associated with the delivery of peptides in vivo. Protein stability and the problem of delivering proteins within their efficacious and safe target doses remain a challenge (see page 39 column 2 3rd paragraph, Brown, Expert Opin Drug Deliv 2:29-42, 2005). Proteins are rapidly eliminated from the circulation through renal filtration, enzymatic degradation,

uptake by the reticulendothelial system and accumulation in non-targeted tissues (see page 259, 2nd column, 3rd paragraph, Torchilin et al Drug Discovery Today:8:259-266, 2003).

The specification does not teach a specific method for targeting the peptide for the delivery to the appropriate site or teach the efficacious uptake at the desired site to prevent the aggregation of GPBP and further the inhibition of tumor-growth or autoimmune disease in a patient. Thus, one could not predict that the half-life of the broadly claimed peptides is sufficient to function as contemplated and inferred, that its stability is sufficient, how many administrations are required in order to function as contemplated and inferred, or even whether or not the claimed peptides are able to function as contemplated and inferred. In view of the above, it would require undue experimentation for one of skill in the art to practice the invention as contemplated and as inferred. Again, it is clear that based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed peptide could be used to treat autoimmune disease, cancer or any other disease, based only on the finding that the peptide are able to inhibit the aggregation and prevent autophosphorylation of the GPBP in vitro.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be reasonably predicted that a method for predicting the peptide will predictably function as disclosed. Therefore, in view of the lack of predictability of the prior art, the breadth of the claims, the lack of guidance and support

in the specification, and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed.

6. Claims 36, 37, 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed has support for any (i.e. generic) 0-10 amino acids of SEQ ID NOs: 41 and 42. However, the specification does not have support for the newly claimed species of "ILATL" in claims 36 and "LMKVR" in claim 37.

Summary

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD
Patent Examiner
571-272-6539

MISOOK YU
PRIMARY EXAMINER

Notice to Comply	Application No. 10/772,656	Applicant(s) Saus et al	
	Examiner Mark Halvorson	Art Unit 1642	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
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